

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
GREAT FALLS DIVISION**

ENVIRONMENTAL DEFENSE FUND;
MONTANA ENVIRONMENTAL
INFORMATION CENTER; and CITIZENS
FOR CLEAN ENERGY,

Plaintiffs,

v.

U.S. ENVIRONMENTAL PROTECTION
AGENCY; and ANDREW R. WHEELER, in
his official capacity as Administrator of
the U.S. Environmental Protection
Agency,

Defendants.

Case No.: 4:21-cv-00003-BMM-JTJ

The Honorable Brian Morris,
Chief Judge

DECLARATION OF LINDA S. BIRNBAUM, PHD

I, Linda Birnbaum, declare as follows:

1. My name is Linda Birnbaum. I am a microbiologist and toxicologist by training. Between 1972 and 1989, I held several academic research posts, including positions at the National Toxicology Program (NTP) at the National Institute of Environmental Health Science (NIEHS). From 1989 to 2009, I held several positions with the Environmental Protection Agency (EPA) including Director, Experimental Toxicology Division, National Health and Environmental Effects Research Library. From 2009 to 2019, I served as the Director of the NIEHS, which is part of the

National Institutes of Health (NIH), and as Director of the NTP. Since 2020, I have been a Scholar in Residence at Duke University's Nicholas School of the Environment.

2. I am a graduate of the University of Rochester and received my MS and PhD in Microbiology from the University of Illinois. I was elected to the National Academy of Sciences' Institute of Medicine in 2010.

3. My professional career has focused on environmental contaminants and their health impacts, including research on endocrine disruptors such as dioxins, polychlorinated biphenyls (PCBs), and polybrominated diphenyl ethers (PBDEs). I have authored more than 800 peer-reviewed papers, reports, book chapters, and abstracts.

4. I am a member of Environmental Defense Fund because I believe in its mission to advocate for science-informed policy and decisionmaking.

5. I understand that EPA Administrator Wheeler signed a rule on December 30, 2020, regarding how EPA may use studies examining "the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect" on human health. *See* 86 Fed. Reg. 469, 470, 492 (Jan. 6, 2021) (codified at 40 C.F.R. § 30.2) ("Rule"). This Rule imposes new restrictions on the ability of EPA to consider such dose-response data for which underlying data cannot

be made “publicly available in a manner sufficient for independent validation.” *Id.* at 492 (codified at 40 C.F.R. § 30.5(c)).

6. Based on my experience as NIEHS Director I am familiar with the process NIEHS and other institutes and centers of the NIH use to evaluate and award grants. I am also familiar with the measures that scientists, universities, grant-giving organizations, and others take to protect, and keep confidential, personal information about human participants in studies.

7. Protecting the confidentiality of both the identity of, and information about, people participating in studies regarding the health effects of pollution and chemicals is a critical and integral part of any study involving human subjects. Such protections are required by laws such as HIPAA, by agreements with the participants, and by conditions placed by universities, grant-giving entities, and other responsible entities through Institutional Review Boards. Ethical considerations, and assurances provided to study participants as an inducement to participate, also mandate that personal information be kept confidential. The grant review process includes careful review of a proposal’s measures to protect confidentiality and compliance with those measures as a condition of any grant.

8. As federally funded programs, NIH and NIEHS grants serve to advance the public interest by providing scientific information that can be used to improve the lives of Americans. In the area of public health, the goal of NIH- and

NIEHS-funded research is to contribute to improving health outcomes for Americans and prevent diseases due to environmental causes. An important factor in awarding grants is whether the research can contribute to the regulatory decisionmaking of federal agencies addressing public health and environmental issues, including EPA. In fact, NIEHS has funding to specifically fund grants related to Superfund sites to inform agency decision-making in those specific areas.

9. NIH and NIEHS grants are an important source of funding for scientists studying the health effects of pollution and chemicals. Environmental epidemiology is both an expensive and intensive effort. Of its approximately \$800 million budget, NIEHS spends approximately \$150 million on projects involving environmental epidemiology. Other NIH institutes such as NHLBI, NICHD, NCI, and the Fogarty Center also fund environmental epidemiology studies. Researchers conducting such observational human studies often have only modest financial support from their home universities and depend on NIH and NIEHS funding to pay their salaries and to support their research centers, including the salaries of other faculty, researchers, and staff who work for them. The ability to receive and sustain NIH or NIEHS funding is critical to the continued financial viability of environmental health research centers.

10. NIH and NIEHS grants are evaluated and awarded through a multi-step process. After initial screening to assure compliance with the extensive

submission requirements, an application is assigned to a peer review panel, typically based on subject matter or the specific Institute that is issuing the grant. The review panel undertakes a careful review of each application using a standard set of scoring criteria. All NIH Institutions score applications based on 5 factors: Significance, Investigator(s), Innovation, Approach, and Environment. Each factor is scored on a scale of 1-9, with a lower score being preferable. The scores are combined to provide a percentile ranking of each application and to assess the overall impact of the proposal to exert a sustained, powerful influence on the research field(s) involved.

11. After review and scoring by the peer panel, applications are reviewed by an Advisory Council or Board for the relevant Institute or Center, which reviews the scoring and evaluates each application based how it aligns with the Institute or Center's priorities and available funding. The Advisory Council makes recommendations to the Institute or Center's director for final awards.

12. NIH and NIEH grants are highly competitive. A higher (poorer) score on any individual scoring element will likely make an application noncompetitive and highly unlikely to receive a grant. Approximately 14% of the grants submitted to NIEHS are funded.

13. An important element of the scoring of grant applications for Significance by the review panel is the impact the research will have. For studies addressing environmental and environmental health issues, the ability for EPA to use

the research to inform decisionmaking is an important consideration in assessing the Significance of an application. If research is unlikely or unable to be used to inform EPA decisionmaking, or will receive limited weight in that decisionmaking, it will receive a higher Significance score and thus be unlikely to receive funding. For example, research applications that examine the health effects of specific chemicals or pollutants that could not be used by EPA would likely be considered to have less Significance than other applications that could produce results that could support agency decision-making, thus making NIH funding unlikely.

14. In addition, some grant funds are tied to specific EPA actions. For example, NIEHS has a stream of funds for grants to address problems associated with Superfund sites. The research funded through those grants is used to help EPA make decisions regarding remediating Superfund sites. If the need to protect the confidentiality of study participants would prevent the results of that study from being used by EPA, or make EPA's use uncertain, the application would receive a high Significance score and would not receive a grant.

15. Further, science is an iterative process and successive research often relies on earlier research and data. If a researcher sought a grant that relied on earlier research but could not obtain permission to make public personal data from the earlier research, that subsequent research may not be able to support EPA decision-

making or receive due weight under the rule. Accordingly, it would receive a higher Significance score and be less likely to be funded.

16. Conversely, due to long-established legal requirements and ethical standards, proposals that do not protect the confidentiality of project participants would also score poorly on the Approach element and would not be funded for that reason. Further, those legal and ethical standards would prevent Institutional Review Boards at host universities and other reviewing institutions from approving research that did not protect the confidentiality of the study subjects.

17. The consequences to researchers of not being able to obtain NIH or NIEHS grants would also be significant and in many cases immediate. Researchers would be deprived of a significant revenue stream, placing their work and the jobs of the researchers and staff they employ at risk.

18. Research itself would suffer. If researchers want to conduct research that could be considered pivotal science warranting full weight by EPA, they would be forced to request that study subjects consent to public disclosure of their personal information, including demographic, socioeconomic, and health information. Most potential subjects would likely not consent, thus impairing the ability of researchers to conduct any research or forcing them to conduct scientifically compromised research. Alternatively, researchers will conduct research using less rigorous methodologies or focus on areas less related to public health where their research

could make a practical difference. In either case, scientific inquiry, public health, and the quality of EPA decisionmaking will be immeasurably harmed. Fundamentally, EPA would be deprived of giving full consideration to the most pertinent, sound scientific information available to make important decisions about how to address health risks posed by the environment and pollutants.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated: January 7, 2021



Linda S. Birnbaum